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K013503
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# Special 510(k) Summary

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| **Name of Sponsor:** | **DePuy Orthopaedics, Inc.**<br>700 Orthopaedic Drive<br>Warsaw, Indiana 46581-0988<br>Est. Reg. No. 1818910 |
| **510(k) Contact:** | **Marcia J. Arentz**<br>Senior Regulatory Associate<br>Phone: (219) 371-4944<br>FAX: (219) 371-4987 |
| **Trade Name:** | **Sterile Colles Classic Fixator** |
| **Common Name:** | External Fixation device |
| **Classification:** | **Class II** Device per 21 CFR 888.3030: Single/Multiple component metallic bone fixation appliances and accessories. |
| **Device Product Code:** | Code: **87KTT** Appliance, Fixation, Nail/Blade/Plate combination, multiple component.<br>No performance standards have been established under Section 514 of the Federal Food, Drug, and Cosmetic Act for femoral hip stems. |
| **Substantially Equivalent Device:** | **Sterile Colles Fixator** **K003397** |
| **Device Descriptions:** | The Colles C Series Frame Sterile Pack is an external fixation device used in the treatment of fractures of the wrist. The system is comprised of half pins that are implanted through the skin attached to adjustable connecting rods that can apply traction. The kit also includes instrumentation required for the surgery. The change to the device is to manufacture part of the clamp from Radel instead of Celcon material. |

K003503

## 510(k) Summary (continued)



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| **Intended use:** | For use in the fixation of distal fractures of the upper extremity. External fixation systems allow control of bone segments including angulation, rotation and displacement. |
| **Indications for use:** | Commuted, intra-articular distal radius fractures (Frykman-Classification III-VIII), Bilateral Colles' fracture, failed closed reduction with casting. |
| **Substantial equivalence:** | The Colles Fixator is the same device cleared in K003397 with the exception of the change to Radel material on the clamp that holds the half pins. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 16 2001

Ms. Marcia J. Arentz
Senior Regulatory Associate
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
P.O. Box 988
Warsaw, Indiana 46581-0988

Re: K013503
Trade/Device Name: Sterile Colles Classic Fixator
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
Regulatory Class: Class II
Product Code: KTT
Dated: October 19, 2001
Received: October 22, 2001

Dear Ms. Arentz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NOV 1 6 2001

**510(k) Number (if known):** K013503

**Device Name: Colles Fixator**

**Indications for Use:**

For use in the fixation of distal fractures of the upper extremity. External fixation systems allow control of bone segments including angulation, rotation and displacement.

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Concurrence of CDRH, Office of Device Evaluation

Prescription Use X
(Per 21 CFR 801.109)

OR Over-The-Counter Use

for

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013503